



WRIST BLOOD PRESSURE MONITOR

User Manual



- Thank you very much for selecting the Actiiv Wrist Blood Pressure Monitor ACMMD001.
- Please read the user manual carefully and thoroughly so as to ensure the safe usage of this product, and keep the manual for further reference in case you have problems.

MODEL: ACMMD001

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♥ General Description

Thank you for selecting the Actiiv blood pressure Monitor (ACMMD001).The monitor features blood pressure measurement, pulse rate measurement and storage of results.

Readings taken by the device are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method.

This manual contains important safety and care information, and provides step by step instructions for using the product.

Please read this user manual carefully and thoroughly before use.

FEATURES:

- Systolic Blood Pressure
- Pulse Rate
- Diastolic Blood Pressure
- Memory: Up to 60 readings can be recorded

♥ Measurement Principle

This product uses the Oscillometric Measuring Method to detect blood pressure. Before every measurement, the unit establishes a "zero point" equivalent to the atmospheric pressure. Then it starts inflating the cuff. Meanwhile, the unit detects pressure oscillation generated by beat-to-beat pulsatile, which is used to determine the systolic pressure and diastolic pressure as well as pulse rate. The device also compares the longest and the shortest intervals of detected pulse wave with the average value, and then calculates the standard deviation. The monitor will light up a warning symbol when the calculated standard deviation is larger than or equal to 15.

♥ Safety information

The below signs might appear in the user manual, labeling or other components.

	Symbol for "THE OPERATION GUIDE MUST BE READ"		Symbol for "TYPE BF APPLIED PARTS"
	For indoor use only		Symbol for "DIRECT CURRENT"
	The Bluetooth Combination Mark	F1	T1A/250V Ø3.6*10CCC

♥ Indications for use

The Actiiv Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and heartbeat rate with a wrist circumference ranging from 13.5 cm to 21.5 cm (about 5-8.5 inches).

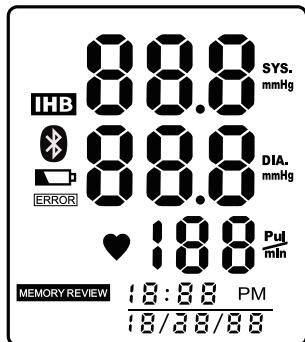
It is intended for adult indoor use only.



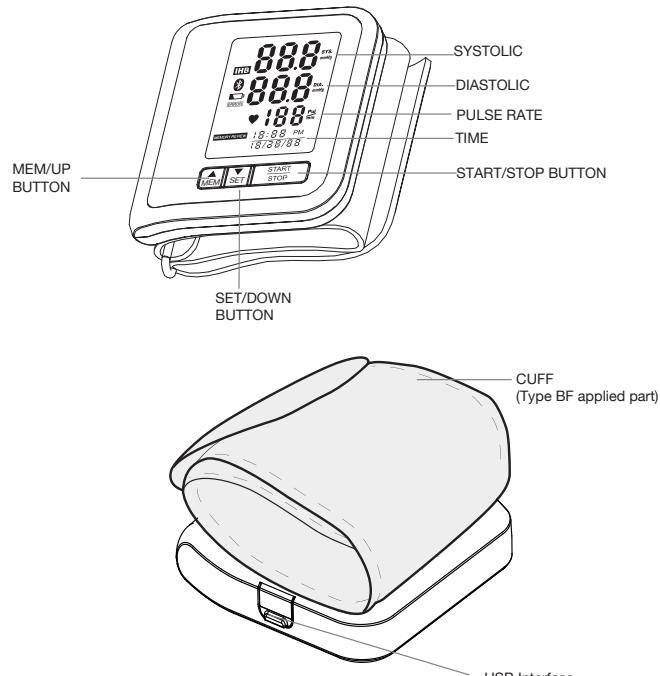
CAUTION

- * It is intended for adult indoor use only. Pregnant women, pre-eclamptic patients and patients with severe obesity should not use this device. If required, please consult a professional doctor.
- * This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the wrist or for functions other than obtaining a blood pressure measurement.
- * Please use the device under the specified environment as instructed in this user manual, otherwise the accuracy of the device will be influenced.
- * Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure. Please only start or end any medical treatments based solely on a physician's treatment advice.
- * If you are taking medication, consult your physician to determine the most appropriate time for your measurement. Never change a prescribed medication without your physician's consent.
- * This unit is not suitable for continuous monitoring during medical emergencies or operations. After the cuff has been inflated for a long time, the patient's wrist and fingers blood supply will become insufficient and could result in distending pain and ecchymosis.
- * If the pressure of the cuff exceeds 40 kPa (300 mmHg), the unit will automatically deflate. If the cuff doesn't deflate when its pressure exceeds 40 kPa (300 mmHg), detach the cuff from the wrist and press the START/STOP button to stop inflation.
- * Do not use the monitor under strong electromagnetic field conditions (e.g. medical RF equipment) that radiate an interference signal or electrical fast transient/ burst signal.
- * The maximum temperature that the applied part can achieve is 42.5°C while the environmental temperature is 40°C.
- * The device is not AP/APG equipment. It is not suitable for use in the presence of a flammable anaesthetic mixture with air (or oxygen, nitrous oxide).
- * Please keep the unit out of reach of infants, children or pets, since inhalation or swallowing of small parts is dangerous or even fatal.
- * Please use the accessories and detachable parts as specified and authorised by the manufacturer. Otherwise, it may cause damage to the unit or danger to the user / patient.
- * The patient is an intended operator. The patient can measure, transmit data and charge the battery under normal circumstances and maintain the device and its accessories according to the user manual.
- * The blood pressure monitor, its adaptor, and the cuff are suitable for use within the patient environment. If you are allergic to dacron or plastic, please don't use this device.
- * This device cannot be used with HF surgical equipment at the same time.
- * There is a PTC current limiter in the monitor, with a specification of 8V and 0.5A. When the voltage and current exceed the limiting value, the monitor will stop working.
- * The device is not suitable for public use.

♥ LCD Display Signal



♥ Monitor Components



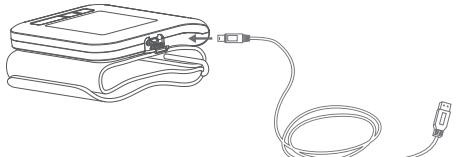
SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic Blood Pressure	High blood pressure
DIA	Diastolic Blood Pressure	Low blood pressure
Pul min	Pulse	beat/minute
Lo	Low Battery	Please use the USB cable provided to recharge the battery.
mmHg	Unit	Measurement unit of blood pressure
IHB	IHB Detector	Irregular Heartbeat Detector
Bluetooth	Bluetooth	Successful Bluetooth Connection
ERROR	Error	Error
MEMORY REVIEW	Memory	Recalling the history records
18:88 PM 18/88/88	Time	Hour:Minute (Month/Day/Year)

♥ List

- 1.Blood Pressure Monitor (ACMMD001)
- 2.USB Cable
- 3.User Manual

♥ Power Supply and Charge Power

1. The battery for ACMMD001 is a built-in rechargeable lithium-ion battery, with a current of 420 mAh.
2. Please use the USB cable provided to charge the battery just like the picture below:



Your device will require charging under the following circumstances:

- +Lo displays on the LCD
- The LCD display dims
- When powering on the monitor, the LCD doesn't light up.



CAUTION

1. The battery used is a built-in rechargeable lithium-ion battery, please do not disassemble it by an unauthorized maintenance personnel.
2. Under normal use, it can be charged about 300 times. If measured three times per day, and the battery is fully charged, it can be used for about 20 days.
3. Store and use the blood pressure monitor in a cool, dry and ventilated environment. Avoid close proximity to fire and heat sources or it may cause the battery explode.
4. You cannot use the blood pressure monitor during the charging process.
5. During the process of charging, the blood pressure monitor will display this symbol: 

When charging is complete, please remove plug before use.

6. When charging, do not touch the charging connector and the patient simultaneously.

♥ Setting Date and Time

Please proceed to set the time before your initial use to ensure each record is labelled with a time stamp. (Year Range: 2012-2052; Time Format: 12 Hours)

1. When the monitor is OFF, press and hold the “SET” button for 3 seconds to enter Time Setting Mode.



2. As pictured in the right, the blinking number “12” representing [HOUR]. Press “MEM” button to change the number. Each press will increase the number by one in a cycling manner.



3. Press “SET” button again to confirm [HOUR]. Then the number representing [MINUTE] blinks.



4. Repeat step 2 and 3 to confirm [MINUTE].



5. Repeat step 2 and 3 to confirm [MONTH], [DAY] and [YEAR].



7. After confirming the [YEAR], the LCD will display "dONE" and the monitor will shut off.



♥ Positioning the Cuff

1. Remove all accessories (watch, bracelet, etc) from your left wrist. If your physician has diagnosed you with poor circulation in your left wrist, use your right wrist.

2. Roll or push up your sleeve to expose the skin.

3. Apply the cuff to your left wrist with your palm facing up.

4. Position the edge of the cuff about 1-2 cm from bottom of hand.

5. Fasten the wrist cuff around your wrist, leaving no extra room between the cuff and your skin. If the cuff is too loose, the measurement will not be accurate.

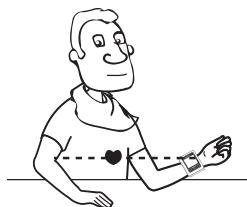
6. Patients with Hypertension:

The middle of the cuff should be at the same level as the right atrium of the heart. Before starting the measurement, please sit comfortably with legs uncrossed, feet flat on the floor, back and arm supported.

- Rest for 5 minutes before measuring.

- Wait at least 3 minutes between measurements. This allows your blood circulation to recover.

- For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same wrist.



♥ Install App and Pair-Up (Supports Bluetooth 4.0 only)

With the advanced Bluetooth 4.0 technology applied to this blood pressure monitor, mobile phones which are equipped with Bluetooth functionality are able to receive your personal health data. Just simply install the specially-designed app and pair up your blood pressure monitor with your mobile phone by following the instructions below

1.The App is now available in the App Store and Google Play.

App name is "LIFESENSE INTERNATIONAL"

You may search for the app, then download and install the app on your iPhone or Android Phone. Simple and convenient!



1. Turn on Bluetooth and the app.
Make sure both are ON when pair-up is proceeding.

2. When the monitor is OFF, press and hold the START button to start pair-up. The symbol and the symbol will be shown on the LCD alternatively, indicating pair-up is proceeding.

IF SUCCESSFULL, symbol will be shown on the LCD.

IF FAILED, symbol will be shown on the LCD.

3. The monitor wil shut off after pair-up process is complete

Bluetooth Module No.: AW2540MV1

RF Frequency Range: 2.4 GHz

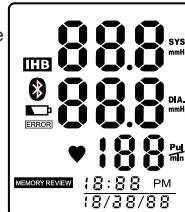
Output Power Range: -1 dBm

Supply Voltage: 2 V to 3.6 V

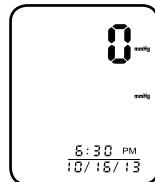
Transmitting Distance: 10 meters

♥ Start Measurement

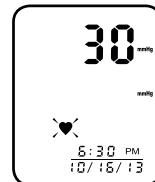
1.After correctly positioning the cuff, press the START button to turn on the monitor, and it will complete the measurement process.



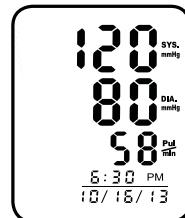
Adjust to zero.



Inflating and measuring.



Display and save the measuring result.



2. The device will proceed to transmit data after taking the measurement.

The Bluetooth symbol blinks on the LCD to indicate data is transmitting to your phone.

3. If the data is successfully transmitted, the LCD will then display “dONE”.

If the data transmission fails, the LCD will display “” instead.

4. Press STOP button to turn off the monitor.



CAUTION

1. When using this device, please pay attention to the following situations which may interrupt blood flow and influence blood circulation of the patient, thus causing harm or injury to the patient: too frequent and consecutive multiple measurements; the application of the CUFF and its pressurization on any wrist where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present; Inflating the cuff on the wrist on the side of a mastectomy.

2. Do not apply the cuff over a wound, otherwise it can cause further injury.

3. Do not inflate the cuff on the same limb which other monitoring ME EQUIPMENT is applied simultaneously, because this could cause temporary loss of function of those simultaneously-used monitoring ME EQUIPMENT.

4. Do not use the device in such a way as to cause prolonged impairment of blood circulation in the patient.

CAUTION

5. The cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the PATIENT. Sensitive people, including pregnant women, pre-eclamptic patients, patients with implanted medical electronic instruments and have atrial fibrillation (AF), premature ventricular beats and peripheral arterial disease (PAD), should avoid using the unit whenever possible.

♥ Recall the Records

1. Press the “MEM” button to access the memory. The monitor will display the calculated average of the last three readings first.



2. Press “MEM/UP” button or “SET/DOWN” button to rotate the history records. “MEM/UP” to go forward; “SET/DOWN” to go backward.



CAUTION

The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (60) is dropped from the list.

♥ Delete the Records

When you have not obtained an accurate measurement, you can clear all the measuring results by following the below steps:

- Under Memory Recalling Mode, press and hold both the "MEM" button and the "SET" button for 3 seconds.



- The LCD will display "dEL dONE", indicating that memory clearing is complete. It will then shutdown.

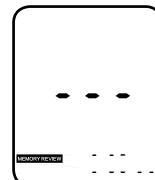


CAUTION

Under Memory Recalling Mode, if you wish to give up clearing, press "START/STOP" to turn off the monitor.



- When there is no memory in the monitor, if you press the "MEM" button to look up the history, the LCD will display as pictured to the right.

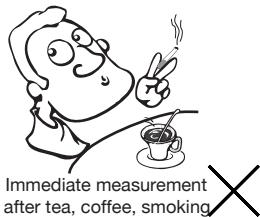


♥ Tips for Measurement

Measurements could be inaccurate if taken in the following circumstances:



Within 1 hour
after eating or drinking



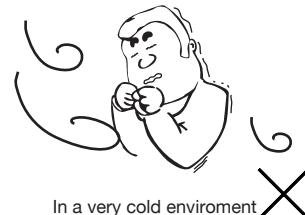
Immediate measurement
after tea, coffee, smoking



Within 20 minutes
after taking a bath



When talking or moving your fingers



In a very cold environment



When you want to discharge urine

♥ Maintenance

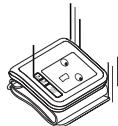
To obtain the best performance, please follow the below instructions.



Keep your device in a cool dry place, avoid direct sunlight and high temperatures



Avoid immersing your device in liquid



Avoid dropping or direct impact



Avoid dusty environments and unstable surrounding temperatures



Use a slightly damp cloth to remove any dirt



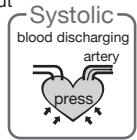
Avoid washing the cuff

CAUTION

1. Please make sure the unit functions safely and that it is in proper working condition before use. Don't service or maintain while the device is in use.
2. If you have any problems with this device, such as setting up, maintaining or using, please go to www.activfitness.com. Don't open or repair the device by yourself.
3. Please report to Activ if any unexpected operation or events occur.
4. Cleaning: Dusty environments may affect the performance of the unit. Please use a soft cloth to remove any dirt from the device and cuff before and after use.

♥ What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.

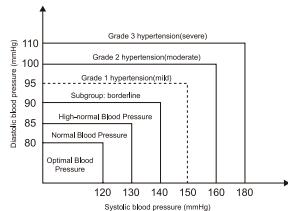


♥ What is the standard blood pressure classification?

The blood pressure classification published by the World Health Organization (WHO) and the International Society of Hypertension (ISH) in 1999 is as follows:

CAUTION

Only a doctor can tell your normal BP range. Please contact your doctor if your measuring result falls out of the range. Kindly note that only a doctor can tell whether your blood pressure value has reached a dangerous point.



Blood Pressure (mm Hg)	Level	Optimal	Normal	High-normal	Mild	Moderate	Severe
SYS	<120	120-129	130-139	140-159	160-179	≥180	
DIA	<80	80-84	85-89	90-99	100-109	≥110	

♥ Irregular Heartbeat Detector

This Blood Pressure Monitor is equipped with an intelligent Irregular Heartbeat (IHB) Detector function. During each measurement, this equipment records the heartbeat intervals and works out the standard deviation. If the calculated value is larger than or equal to 15, this equipment will light up the IHB symbol on the screen when displaying the measuring result.

CAUTION

The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

♥ Why does my blood pressure vary, even in one day?

1. Individual blood pressure varies every day. It is also affected by the way you tie your cuff and your measurement position, so please take the measurement in the same conditions.

2. Blood pressure variation is greater if the person takes medication.

3. Make sure you wait at least 3 minutes before taking another measurement.



♥ Why is the blood pressure I get from the hospital different from home?

Blood pressure can vary even during a 24 hour period due to influences like the weather, emotions, exercise etc. You may experience different environmental and emotional conditions at a hospital compared to at home which can affect your blood pressure measurements.

♥ Will I get the same result if I measure on the right wrist?

It is ok to use the device on both wrists, but the results may differ depending on the person. It is recommended that you measure on the same wrist every time to maintain an accurate record of measurements.



This section includes a list of error messages and frequently asked questions for problems you may encounter with your blood pressure monitor. If the product is not operating as you think it should, check here before contacting support.

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display is dim or will not light up.	Power is exhausted.	Charge the power
Low batteries	+ Show on the display	Power is low.	Charge the power
Error message	shows	Data communication has failed	Make sure that phone's Bluetooth is on or within the distance range
	E 2 shows	The cuff is very tight	Refasten the cuff and then measure again.
	E 3 shows	The pressure of the cuff is in excess.	Relax for a moment and then measure again.
	E 9 shows	Product has not been activated.	Reactivated
	E 10 or E 11 shows	The monitor detected motion while measuring.	Movement can affect the measurement. Relax for a moment and then measure again.
	E 20 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again.
	E 21 shows	Measured incorrectly.	Relax for a moment and then measure again.
	EExx shows on the display.	A calibration error occurred.	Retake the measurement. If the problem persists, contact the retailer or our customer service department for further assistance.

Power supply	3.7V 420mAH Built-in rechargeable lithium-ion battery, 5V / 1A USB
Display	Digital LCD V.A.46.5x36.5mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0kpa-40kpa (0mmHg-300mmHg) Measurement pressure: 4kPa-34kPa (30mmHg-255mmHg) pulse value:(40-199)beat/minute
Accuracy	Pressure: 5°C-40°C within±0.4kpa(3mmHg) 0°C-45°C (out of 5°C-40°C) within±0.7kpa(5mmHg) pulse value:±5%
Normal working condition	Temperature:5°C to 40°C Relative humidity ≤85% Atmospheric pressure: 86kPa to 106kPa
Storage & transportation condition	Temperature:-20°C to 60°C RH: 10% to 93% Atmospheric pressure: 50kPa to 106kPa
Measurement perimeter of the wrist	About 13.5cm-21.5cm
Net Weight	Approx.110g
External dimensions	Approx.79.8x72.5x13.2mm
Attachment	USB cable, User manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP22, It means the device could be protected against solid foreign objects of 12.5 mm and greater, and against vertically falling water drops when ENCLOSURE is tilted up to 15°
Software version	V01
Device classification	Battery Powered Mode: Internally Powered ME Equipment

♥ Contact Information

For customer support, please visit www.actiivfitness.com

♥ Complied European Standards List

Risk management	ISO/EN 14971:2012 Medical devices – Application of risk management to medical devices
Labeling	ISO/EN 15223-1:2012 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
User manual	EN 1041: 2008 Medical equipment manufacturers to provide information
General Requirements for Safety	<p>IEC/EN 60601-1: 2006+A1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance</p> <p>IEC/EN 60601-1-11: 2010 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment</p> <p>IEC/EN 80601-2-30:2009 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers</p>
Electromagnetic compatibility	IIEC/EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
Performance requirements	<p>EN 1060-1:1995+A2:2009 Non-invasive blood pressure Part 1: General requirements</p> <p>EN 1060-3:1997+A2:2009 Non-invasive blood pressure Part 3: Supplementary requirements for electromechanical blood pressure measuring system</p>
Clinical investigation	EN 1060-4: 2004 Automatic Blood Pressure Monitor overall system Interventional accuracy of the testing process
Usability	<p>IEC/EN 60601-1-6: 2010 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability</p> <p>IEC/EN 62366: 2007 Medical devices - Application of usability engineering to medical devices</p>
Software life-cycle processes	IEC/EN 62304:2006+AC: 2008 Medical device software - Software life cycle processes

♥ EMC Guidance

1. The Blood Pressure Monitor needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS

2. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance $d = 3,3$ m away from the equipment.

(Note. As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields $d = 3,3$ m at an IMMUNITY LEVEL of 3 V/m)

Installing App and Pairing

The following steps are for use with iPhone.

The App is also available for Android through Google Play.

1. Search for the App in the App Store. The App name is "Lifesense International". Download and install the App onto your phone.
2. Ensure Bluetooth is turned "ON" on your phone
3. Run the App, the following screen should appear
4. Create a new account or sign in



5. The following screen will appear after you have signed in.



6. Press "Edit" at the bottom right corner, untick "Weight", press the back button and "Yes" to save Data. (this will remove the weight measurement) and return to the Start menu.
7. Press the "Settings" button in the top right corner (⚙)
8. Press the "Add" button to add a device (+)



9. Press the Bluetooth logo



10. Please ensure you press and hold the "Start" button on the blood pressure monitor to initiate Pairing Mode.

11. Once connected, the device will show []. It is now ready to use.

12. Your readings will be recorded on the App, you can find the readings by selecting Blood Pressure in the App as per the image shown here



13. The following screen will appear



14. To see records, press the "list" button at the top of the screen (≡)

15. The following screen will appear



16. To delete any unwanted readings, slide to the left on the reading and the delete button will appear

